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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER PREBILIC, PAUL B	
			ART UNIT 3738	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/624,981

Applicant(s)

ZDEBLICK ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 61-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 61-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 66-68, 72, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich et al (US 5,458,638) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kuslich et al (US 5,458,638) alone. Kuslich anticipates the claim language where the occlusion body as claimed is the cap (147) of Kuslich, the anchor as claimed is the clip (148), and the lip as claimed is the barb ((61) or end of clip (148)); see Figures 10, 12A, 13A, 15, 18-20, and 25 as well as column 8, line 38 et seq. It is noted that the "hollow fusion device" is not positively claimed, and therefore, any language referring to it only infers structure to the cap. Therefore, the cap (10) of Kuslich could be used on a device like device (14) but smaller so that the prongs or

clips (60) or (148) would reach to an opening displaced from opening (142). The effective filing date of the present claims is February 11, 1997.

Alternatively, one could interpret the claims as implying structure of the cap, based upon the references to the hollow fusion device, that it different from the cap of Kuslich. However, such a structure would have been obvious in view of Kuslich alone because the clips of Kuslich engage the interior edge of opening (142) and the thru-hole runs through the interior of the body portion (122). Therefore, it would have been at least *prima facie* obvious to make the clips of a length to engage some other edge such as a thru-hole edge to secure it to the fusion device.

With regard to claim 2 specifically, the flange is the position of the cap (149) that extends past the clips (148).

With regard to claim 66, the curved profile is between the barb and clip.

With regard to claim 68, Applicants are directed to column 7, lines 13-30.

Claims 75-81 and 87-92 are rejected under 35 U.S.C. 102(e) as being anticipated by Biedermann et al (US 5,702,451) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Biedermann (US 5,702,451) alone. Biedermann anticipates the claim language where the cap as claimed is the member (11) as shown in Figures 6-11. The edge portion (20) engages the jacket (1) to cap the end. It is noted that the "hollow fusion device" is not positively claimed so the cap merely needs to be capable of being used with a hollow fusion device with the structure inferred thereby. The Examiner asserts that the prongs of Biedermann are fully capable of engaging a thru-hole edge at the second or far end.

Alternatively, one could interpret the claims as implying structure of the cap, based upon the references to the hollow fusion device, that it different from the cap of Biedermann. However, such a structure would have been obvious in view of Biedermann alone because the clips of Biedermann are capable of contacting or engaging the interior surface of a hollow fusion device. Therefore, it would have been at least *prima facie* obvious to make the prongs of Biedermann capable of engaging the interior of the fusion device as a means to frictionally secure the two structures to each other.

Regarding claims 80 and 81, the second anchor as claimed is met by prong (21') even though it is not directly attached to the ring (12) of the member (11).

Claims 75 and 77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich et al (US 5,458,638) alone. Kuslich discloses a rounded outer surface for the cap (147) of the disclosed embodiment and not the flat outer surface as claimed. However, the Examiner asserts that it would have been *prima facie* obvious to make the cap of Kuslich at least partially flat on the outer surface when used on the same end as cap (18") of Kuslich for the same reasons that Kuslich does the same in that embodiment.

Claims 61, 62, 65, 74, 76, 87, 88, 93, and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich et al (US 5,458,638) in view of Biedermann et al (US 5,702,461) or Ray et al (WO 91/06261). Kuslich meets the claim language as explained in the Section 102 rejection *supra*, but fails to disclose apertures in the cap as claimed. However, Biedermann (see Figures 3 and 5) or Ray (see Figure 1) teaches

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that it was known to put apertures in similar devices that are inherently capable of allowing ingrowth and protein ingress due to their macroscopic size. Therefore, it is the Examiner's position that it would have been obvious to put apertures in the plate of Kuslich for the same reasons that Biedermann or Ray does the same and in order to better promote fusion.

Regarding claim 65, Applicants are directed to Figures 8 and 13A that shows a flat surface on the outer wall for a different cap. For this reason, the Examiner asserts that it would have been *prima facie* obvious to make the cap of Kuslich at least partially flat on the outer surface when used on the same end as cap (18") of Kuslich.

With regard to claim 97 specifically, the configuration or shape of the lip as having a curved profile to match the surface it is to be mated with is "considered to a matter of choice that a person of ordinary skill would have found obvious absent persuasive evidence that the particular configuration . . . was significant"; see MPEP 2144.04 IV B that it incorporated herein by reference thereto.

MPEP 2144.04 IV B. Changes in Shape

In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.)

Claims 1, 2, 61-64, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al (US 5,702,451) in view of Kuslich et al (US 5,458,638). Biedermann discloses a cap member (11) with an occlusion body (plate ring (12)) from which an anchor (edge (20)) that projects; see Figures 6-11. However,

Biedermann fails to disclose lip on the second end as claimed. However, Kuslich teaches that it was known to make similar caps with lips (i.e. barbs) as a means to hold the cap in place. Therefore, it is the Examiner's position that it would have been obvious to put lips or barbs on the terminal edges of edge (20) in order to more securely hold it to the jacket (1).

Claims 69, 82, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich et al (US 5,458,638) in view of Michelson (US 2002/0138144). Kuslich meets the claim language as explained in the Section 102 rejection therewith *supra*, but fails to teach making the plate and arms bioabsorbable or coated with a bioabsorbable material such as hydroxyapatite. However, Michelson teaches that it was known to make similar caps in similar devices biodegradable or bioabsorbable; see paragraph [0056]. Therefore, it is the Examiner's position that it would have been obvious to make the cap of Kuslich bioabsorbable or biodegradable for the same reasons that Michelson does the same or in order to make the device more open to ingrowth once sufficient ingrowth has occurred to stabilize the bone chips within the device. This additional openness would improve the fusion capabilities of the device.

Claims 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al (US 5,702,451) in view of Michelson (US 2002/0138144). Biedermann meets the claim language as explained in the Section 102 rejection therewith *supra*, but fails to teach making the member (11) bioabsorbable polymer. However, Michelson teaches that it was known to make similar caps in similar devices

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biodegradable or bioabsorbable; see paragraph [0056]. Therefore, it is the Examiner's position that it would have been obvious to make the cap of Biedermann bioabsorbable or biodegradable for the same reasons that Michelson does the same or in order to make the device more open to ingrowth once sufficient ingrowth has occurred to stabilize the bone chips within the device. This additional openness would improve the fusion capabilities of the device.

Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich, Biedermann, and Ray as applied to claims 61, 62, 65, 74, 76, 87, 88, 93, and 97 above, and further in view of Michelson (US 2002/0138144). Kuslich fails to teach making the plate and arms bioabsorbable or coated with a bioabsorbable material such as hydroxyapatite. However, Michelson teaches that it was known to make similar caps in similar devices biodegradable or bioabsorbable; see paragraph [0056]. Therefore, it is the Examiner's position that it would have been obvious to make the cap of Kuslich bioabsorbable or biodegradable for the same reasons that Michelson does the same or in order to make the device more open to ingrowth once sufficient ingrowth has occurred to stabilize the bone chips within the device. This additional openness would improve the fusion capabilities of the device.

Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (US 5,458,638) in view of Michelson (US 6,605,089). Kuslich failed to disclose the use of a porous material to make the body or plate as claimed. However, Michelson teaches that it was known to make similar devices in the art of porous materials; see claim 49 thereof. Therefore, it is the Examiner's position that it would have been

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obvious to make the plate of Kuslich porous for the same reasons that Michelson did the same or in order to promote ingrowth, ongrowth, and spinal fusion as is desired by Kuslich.

Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann (US 5,702,451) in view of Michelson (US 6,605,089). Biedermann failed to disclose the use of a porous material to make the body or plate as claimed. However, Michelson teaches that it was known to make similar devices in the art of porous materials; see claim 49 thereof. Therefore, it is the Examiner's position that it would have been obvious to make the plate of Biedermann porous for the same reasons that Michelson did the same or in order to promote ingrowth, ongrowth, and spinal fusion as is desired by Biedermann.

Claims 71 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann and Michelson (US 6,605,089) as applied to claim 84 above, and further in view of Robine (FR 2,710,519). Biedermann fails disclose the use of a threaded hole for an instrument as claimed. However, Robine teaches that such was known; see Figures 1 to 4. Therefore, it is the Examiner's position that it would have been obvious to put a threaded instrument hole in the Biedermann plate for the same reasons that Robine does the same and in order to aid in the insertion thereof.

Claim 96 is rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann (US 5,702,451) in view of Robine (FR 2,710,519). Biedermann fails disclose the use of a threaded hole for an instrument as claimed. However, Robine teaches that such was known; see Figures 1 to 4. Therefore, it is the Examiner's

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position that it would have been obvious to put a threaded instrument hole in the Biedermann plate for the same reasons that Robine does the same and in order to aid in the insertion thereof.

Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich, Biedermann, and Ray as applied to claims 61, 62, 65, 74, 76, 87, 88, 93, and 97 above, and further in view of Michelson (US 6,605,089). Kuslich failed to disclose the use of a porous material to make the body or plate as claimed. However, Michelson teaches that it was known to make similar devices in the art of porous materials; see claim 49 thereof. Therefore, it is the Examiner's position that it would have been obvious to make the plate of Kuslich porous for the same reasons that Michelson did the same or in order to promote ingrowth, ongrowth, and spinal fusion as is desired by Kuslich.

Claims 98-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann in view of Michelson (US 6,605,089). Kuslich failed to disclose the use of a porous material to make the body or plate as claimed. However, Michelson teaches that it was known to make similar devices in the art of porous materials; see claim 49 thereof. Therefore, it is the Examiner's position that it would have been obvious to make the plate of Biedermann porous for the same reasons that Michelson did the same or in order to promote ingrowth, ongrowth, and spinal fusion as is desired by Biedermann.

Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann and Michelson (US 6,605,089) as applied to claims 98-103 above, and further in view of Kuslich (US 5,458,638). Biedermann failed to disclose the use of a lip

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with a curved profile on the anchors as claimed. However, Kuslich teaches that it was known to make similar caps with lips (i.e. barbs) as a means to hold the cap in place. For this reason, it is the Examiner's position that it would have been obvious to put lips or barbs on the terminal edges of edge (20) in order to more securely hold it to the jacket (1).

The configuration or shape of the lip as having a curved profile is "considered to a matter of choice that a person of ordinary skill would have found obvious absent persuasive evidence that the particular configuration . . . was significant"; see MPEP 2144.04 IV B that it incorporated herein by reference thereto.

MPEP 2144.04 IV B. Changes in Shape

In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.)

Claims 71, 85, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich and Michelson as applied to claim 70 above, and further in view of Robine (FR 2,710,519). Kuslich fails disclose the use of a threaded hole for an instrument as claimed. However, Robine teaches that such was known; see Figures 1 to 4. Therefore, it is the Examiner's position that it would have been obvious to put a threaded instrument hole in the Kuslich plate for the same reasons that Robine does the same and in order to aid in the insertion thereof.

Response to Arguments

Applicant's arguments filed June 18, 2007 have been fully considered but they are not persuasive.

With regard to the traversal of the Kuslich rejection that the length of the anchor is not sufficient to engage a throughhole, the Examiner has found this unpersuasive since the fusion device is not positively required by the present claim language. Consequently, the cap need only be capable of being utilized with a fusion device such that it is capable of engaging a thru-hole therein. The cap (20) of Kuslich is fully capable of being used to block an opening and engage a through hole. For example, the openings (130) could be flush with the inside surface of ribs (146) to form a through hole; see Figure 14. Then the cap would engage a through hole as inferentially required. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Furthermore, the Kuslich cap is shown engaging the edges of a throughhole in Figures 12A and 13A, for example. For this reason, even though Kuslich calls the hole edges engaged "a rib" (146), the Examiner asserts that the rib can be the edge of a throughhole to the extent that this language can be given patentable weight. Furthermore, there is nothing that would prevent this same device from engaging another hole where there were not ribs adjacent the openings only indentations in the wall of the hole.

With regard to the traversal of the Biedermann rejection that the prongs do not engage the fusion device, the Examiner again asserts that the fusion device is not positively required by the claim language. For this reason, as long as the cap of Biedermann is capable of being utilized in the manner claimed, with any sort of fusion device, the claim language is fully met. Contrary to the Applicant's assertion that all the claim limitations are not met by Biedermann, the Examiner asserts that all the limitations positively recited or inferentially suggested are fully present in the Biedermann device.

Furthermore, if interpreting the Applicant's remarks as requiring the prongs to be outside the jacket, the noses (15) that are radially outside the prongs (21, 21') could not lie in the V-shaped recesses (9, 10) if the prongs were outside the jacket while engaged therewith. Rather, Biedermann must mean that the prongs extend away from the edge (7 or 8) of the jacket but within the interior of the jacket. Note that the outer contour of edge portion (20) corresponds to the inner contour of the jacket; see column 3, lines 1-2.

Additionally, the Examiner asserts that the disclosure of "prongs extending beyond the edge 7 or 8" refers to the prongs extending inside the jacket so far that they extend beyond the edges 7 or 8 of the bottom of the V-shaped recesses (9,10) almost to the base of the V's; see Figure 1 and column 3, lines 5-8.

Finally, since the edge (20) is designed to match the contour of the inner jacket surface, it would implicitly engage the inner jacket to the extent required by the claims. By "engage", the Examiner is interpreting the term in its broadest reasonable form to mean in a position of operation.

With regard to the traversal of the Kuslich in view of Biedermann rejection that Kuslich that the modification suggested renders Kuslich unsuitable for its intended purpose, the Examiner asserts that this is not true. This argument assumes that the disk material is small enough to migrate out of the apertures in a significant amount. This is not suggested the by applied art. Moreover, it is certainly well within the ability of PHOISTA to make the material in such a way that it would not migrate out during insertion. For example, the tool could be made to block the openings during insertion.

The Applicant continues with this sort of distorted analysis of the other rejections alleging reasons as to why the combinations would render the invention unsatisfactory for its intended purpose. Such arguments are not considered persuasive because they are not fair assessments of the prior art and what it teaches.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
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